Clinical Research Laboratories, LLC

CLINICAL STUDY REPORT

Report Status:	Final Report
Report Date:	October 12, 2016
CRL Study Number:	CRL2016-0601
Client Study Number:	JA900-DAA-5-01 JA900-DAA-5-02
CRL Protocol Number:	CL 1.0 2016
Study Dates:	July 18, 2016 - August 26, 2016
Study Title:	Repeated Insult Patch Test (RIPT) –Shelanski Method
Test Material:	- JA900-DAA-5-01 - JA900-DAA-5-02
Sponsor:	International Flavors & Fragrances Inc. 800 Rose Lane Union Beach, NJ 07735
Sponsor Representative:	Xiao Huang Regulatory Manager
Principal Investigator:	Anita Lee Cham, M.D. Dermatologist

APPROVAL SIGNATURES:

Anita Lee Cham, M.D.

Digitally signed by Anita Lee Cham, M.D.
DN: cn=Anita Lee Cham, M.D., o=Clinical Research Laboratories, LLC, ou, email=anita.cham@crlresearchlabs.com, c=US
Date: 2016.10.12 15:08:38 -04'00'

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Principal Investigator Signature/Date

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Good Clinical Practice
Quality Assurance Audit Statement

Clinical Study Number: CRL2016-0601

Start Date: July 18, 2016

Completion Date: August 26, 2016

The clinical study listed above was conducted in accordance with Clinical Research Laboratories, LLC Standard Operating Procedures, which incorporate the principles of Good Clinical Practice defined by applicable guidelines and regulations established by U.S. Regulatory Agencies. The conduct of the study was monitored for compliance, and the associated records, including source documents and/or raw data, were reviewed for documentation practices and accuracy by the Principal Investigator and/or a Quality Assurance representative. Standard Quality Assurance audit procedures for this final report and study related documents were conducted.

Karen Hoyberg

Digitally signed by Karen Hoyberg
DN: cn=Karen Hoyberg, o=Clinical Research Laboratories, LLC, ou=Regulatory/Quality Assurance, email=karen.hoyberg@crlresearchlabs.com, c=US
Date: 2016.10.12 09:37:13 -04'00'

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Quality Assurance Auditor Signature/Date

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FINAL REPORT

Repeated Insult Patch Test (RIPT) - Shelanski Method

1.0 SUMMARY

One hundred thirteen subjects participated in evaluating the potential of JA900-DAA-5-01 and JA900-DAA-5-02 to elicit dermal irritation and/or induce sensitization. The test materials were applied under occlusive patches to the upper back of each subject and were allowed to remain in direct skin contact for a period of 24 hours. Patches were applied to the same site on Monday, Wednesday, and Friday for a total of 9 applications during the Induction Period. The sites were graded by a CRL technician for dermal irritation 24 hours after removal of the patches by the subjects on Tuesday and Thursday and 48 hours after removal of the patches on Saturday

Approximately 10 to 21 days after the Induction Phase, challenge patches were applied to previously untreated test sites on the back. After 24 hours, the patches were removed by a CRL technician and the test sites were evaluated for dermal reactions. The test sites were re-evaluated at 48 and 72 hours after application. Subjects exhibiting reactions during the Challenge Phase of the study may have been asked to return for a 96-hour reading.

One hundred twelve subjects completed the study. The test materials identified as JA900-DAA-5-01 and JA900-DAA-5-02 did not demonstrate a potential for eliciting dermal irritation or sensitization under the following test conditions: 0.15 ml of the test material applied to a 3.63 cm^2 occlusive patch.

2.0 OBJECTIVE

The objectives of this study were to determine the potential of a test material to elicit dermal irritation or induce sensitization following repeated patch applications.

3.0 PRINCIPAL INVESTIGATOR/INVESTIGATIVE SITE

Anita Lee Cham, M.D.
Dermatologist

Clinical Research Laboratories, LLC
371 Hoes Lane, Suite 100
Piscataway, New Jersey 08854
732-981-1616

4.0 SPONSOR REPRESENTATIVE/SPONSOR

Xiao Huang
Regulatory Manager

International Flavors & Fragrances Inc.
800 Rose Lane
Union Beach, NJ 07735

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5.0 TEST MATERIAL

The following test materials were provided by International Flavors & Fragrances Inc. and were received by Clinical Research Laboratories, LLC on July 1, 2016.

Test Material	Test Condition	Patch Type
JA900-DAA-5-01	0.15 ml of the test material was applied to a 3.63cm^2 patch. The test material was applied to the patch as received and allowed to evaporate for at least 30 minutes, but no longer than 90 minutes, prior to patch application.	Occlusive*
JA900-DAA-5-02	0.15 ml of the test material was applied to a 3.63cm^2 patch. The test material was applied to the patch as received and allowed to evaporate for at least 30 minutes, but no longer than 90 minutes, prior to patch application.	Occlusive*

The test materials were coded with the following CRL identification number:

CRL2016-0601-1
CRL2016-0601-2

6.0 STUDY DATES

This study was initiated on July 18, 2016 and was completed on August 26, 2016.

7.0 PANEL SELECTION

Each subject was assigned a permanent CRL identification number. All subjects signed an Informed Consent Form in compliance with 21 CFR Part 50: "Protection of Human Subjects" and a HIPAA Authorization Form in compliance with 45 CFR Parts 160 and 164. All subjects completed a Subject Profile provided by Clinical Research Laboratories, LLC prior to the study (Subject Demographics - Appendix I). Subjects who met the following Inclusion Criteria and none of the Exclusion Criteria were impaneled:

7.1. INCLUSION CRITERIA

A subject may be eligible for enrollment provided the following criteria are met:

a. Subject is male or female between the ages of 18 and 70 years;

b. Subject does not exhibit any skin diseases or abnormalities which might be confused with a skin reaction from the test material;

c. Subject agrees to avoid exposure of the test sites to the sun and to refrain from visits to tanning salons during the course of this study;

*Occlusive Strip with Flexcon® (Strukmyer LLC, Mesquite,TX or equivalent)

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7.0 PANEL SELECTION (Continued)

7.1 INCLUSION CRITERIA (CONTINUED)

d. Subject agrees to refrain from getting patches wet and from scrubbing or washing the test area with soap or applying powders, lotions or personal care products to the area during the course of the study;

e. Subject has signed an Informed Consent in conformance with 21 CFR Part 50: "Protection of Human Subjects";

f. Subject has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;

g. Subject is in generally good health and has a current Subject Profile/Medical History on file at CRL;

h. Subject is dependable and able to follow directions as outlined in the protocol.

7.2. EXCLUSION CRITERIA

A subject may not be eligible for enrollment if any of the following criteria are met:

a. Subject is pregnant, nursing, or planning to become pregnant;

b. Subject is currently using any systemic or topical corticosteroids, anti-inflammatory drugs, or antihistamines on a regular basis;

c. Subject reports allergies to cosmetics, toiletries, latex or personal care products;

d. Subject exhibits any skin disorders, sunburn, scars, excessive tattoos, etc. in the test area;

e. Subject has scheduled, or planning to undergo m any medical or surgical procedures during the 6 week course of the study.

f. Subject who have reacted to an IFF test material within the past year.

8.0 TEST METHOD SUMMARY

This study was conducted using a modified Shelanski – Shelanski human patch test method*. Prior to the application of the patches, the test areas werewiped with 70% isopropyl alcohol and allowed to dry. The test materials, whichwere prepared as described in the Test Material section of the report, were applied to the upper back (between the scapulae and the waist to either side of the spinal midline) and were allowed to remain in direct skin contact for a period of 24 hours.

*H.A. Shelanski and M.V. Shelanski, Proc. Sci. Sect. Toilet Goods Assoc. 19:46, 1953.

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8.0 TEST METHOD SUMMARY (Continued)

Patches were applied to the same sites on Monday, Wednesday, and Friday for a total of 9 applications during the Induction Period. This schedule may have been modified to allow for inclement weather, missed visits or holidays. If a subject was unable to report on an assigned test date, the test material was applied on 2 consecutive days during the Induction Phase and/or a makeup day was added at the end of the Induction Phase.

The sites were graded by a CRL technician for dermal irritation 24 hours after removal of the patches by the subjects on Tuesday and Thursday and 48 hours after removal of the patches on Saturday, unless the patching schedule was altered as described above.

The sites were graded according to the following scoring system:

Dermal Scoring Scale

0	No visible skin reaction
±	Barely perceptible erythema
1+	Mild erythema
2+	Well defined erythema
3+	Severe erythema and edema
4+	Erythema and edema with vesiculation

If a "2+" reaction or greater occurred, the test material was applied to an adjacent virgin site. If a "2+" reaction or greater occurred on the new site, the subject may not have been patched again during the Induction Phase but may have been challenged on the appropriate day of the study. At the discretion of the Study Director, patch sites with scores less than a "2+" may have been changed.

Approximately 10 to 21 days after the Induction Phase, the challenge patches were applied to previously untreated test sites on the back. After 24 hours, the patches were removed by a CRL technician and the test sites were evaluated for dermal reactions. The test sites were re-evaluated at 48 and 72 hours after application. Subjects exhibiting reactions during the Challenge Phase of the study may have been asked to return for a 96-hour reading.

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9.0 PROTOCOL DEVIATIONS

The following protocol deviations occurred:

- Subjects #49 and #53 missed the 9th Induction evaluation but did receive 9 induction patches.

These deviations had no impact on the scientific validity or outcome of the study and did not affect the safety of the subjects.

10.0 RESULTS

This study was initiated with 113 subjects. One subject discontinued study participation for reasons unrelated to the test material. A total of 112 subjects completed the study.

Individual dermal scores recorded during the Induction and Challenge Phases appear in Table I.

11.0 ADVERSE EVENTS

No adverse events were reported during the study.

12.0 CONCLUSION

Based on the test population of 112 subjects and under the conditions of this study, the test materials identified as JA900-DAA-5-01 and JA900-DAA-5-02 did not demonstrate a potential for eliciting dermal irritation or inducing sensitization under the following test conditions: 0.15ml of the test material applied to a 3.63 cm^2 occlusive patch.

13.0 RETENTION

Test materials and all original forms of this study will be retained by Clinical Research Laboratories, LLC as specified in CRL Standard Operating Procedures 30.6 and 30.6C, unless designated otherwise by the Sponsor.

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Table I - Summary of Dermal Scores

Test Material:	JA900-DAA-5-01

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	±	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-01

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
26	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	X	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0

X = Subject Absent

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-01

Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
51	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	X	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0
55	Discontinued											
56	0	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0	0
61	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0

X = Subject Absent

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-01

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
76	0	0	0	0	0	0	0	0	0	0	0	0
77	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	0	0	0	0	0	0	0	0
79	0	0	0	0	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0	0	0	0	0
81	0	0	0	0	0	0	0	0	0	0	0	0
82	0	0	0	0	0	0	0	0	0	0	0	0
83	0	0	0	0	0	0	0	0	0	1+	±	0
84	0	0	0	0	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0
93	0	0	0	0	0	0	0	0	0	0	0	0
94	0	0	0	0	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0	0	0	0	0
96	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0
99	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0	0	0

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-01

Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
101	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	0	0	0	0	0	0	0	0
103	0	0	0	0	0	0	0	0	0	0	0	0
104	0	0	0	0	0	0	0	0	0	0	0	0
105	0	0	0	0	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0
109	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	0	0	0	0	0
111	0	0	0	0	0	0	0	0	0	0	0	0
112	0	±	±	0	0	0	0	0	0	0	0	0
113	0	0	0	0	0	0	0	0	0	0	0	0

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-02											
Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-02											
Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
26	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	X	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0

X = Subject Absent

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-02											
Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
51	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	X	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0
55	Discontinued											
56	0	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0	0
61	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0

X = Subject Absent

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-02											
Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
76	0	0	0	0	0	0	0	0	0	0	0	0
77	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	0	0	0	0	0	0	0	0
79	0	0	0	0	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0	0	0	0	0
81	0	0	0	0	0	0	0	0	0	0	0	0
82	0	0	0	0	0	0	0	0	0	0	0	0
83	0	0	0	0	0	0	0	0	0	1+	±	0
84	0	0	0	0	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0
93	0	0	0	0	0	0	0	0	0	0	0	0
94	0	0	0	0	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0	0	0	0	0
96	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0
99	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0	0	0

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Table I - Summary of Dermal Scores (continued)

Test Material:	JA900-DAA-5-02											
Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
101	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	0	0	0	0	0	0	0	0
103	0	0	0	0	0	0	0	0	0	0	0	0
104	0	0	0	0	0	0	0	0	0	0	0	0
105	0	0	0	0	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0
109	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	0	0	0	0	0
111	0	0	0	0	0	0	0	0	0	0	0	0
112	0	±	0	0	0	0	0	0	0	0	0	0
113	0	0	0	0	0	0	0	0	0	0	0	0

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Appendix I - Subject Demographics

Subject Number	Subject Initials	Age	Sex
1	AJ	67	F
2	AM	53	M
3	EM	24	F
4	TG	29	F
5	CD	30	F
6	SC	52	F
7	SL	39	F
8	DH	47	F
9	RG	56	F
10	CP	40	F
11	LE	48	F
12	JB	61	F
13	LC	54	F
14	SB	44	F
15	DP	51	F
16	HH	55	F
17	RS	48	F
18	EJ	68	F
19	TC	41	F
20	FP	61	F
21	RP	65	M
22	MK	64	M
23	SB	69	F
24	AS	18	F
25	DK	22	M
26	DR	57	F
27	MB	52	F
28	JB	57	M

Subject Number	Subject Initials	Age	Sex
29	MC	59	M
30	GK	31	M
31	RT	38	F
32	LK	66	F
33	LD	53	M
34	HH	29	F
35	PM	58	F
36	SS	58	F
37	LW	63	F
38	JW	60	F
39	LW	59	F
40	JR	38	F
41	DB	23	F
42	MM	39	F
43	SM	51	F
44	KE	20	F
45	KS	51	F
46	RG	60	F
47	CD	53	F
48	NR	66	F
49	RI	52	F
50	JO	64	M
51	AS	43	F
52	GP	69	F
53	NC	38	F
54	NP	42	F
55	JA	23	F
56	BC	51	F

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Appendix I - Subject Demographics (continued)

Subject Number	Subject Initials	Age	Sex
57	NB	37	F
58	FB	46	F
59	PE	53	F
60	LB	57	F
61	DK	52	M
62	BW	61	F
63	SR	58	M
64	MV	45	F
65	SS	32	M
66	WA	58	F
67	AC	55	F
68	AH	61	M
69	RP	30	F
70	JS	55	F
71	LG	48	F
72	DM	30	F
73	KH	51	F
74	LE	28	F
75	AM	63	M
76	DB	58	F
77	JA	43	M
78	YM	38	F
79	FL	59	M
80	BP	61	F
81	BR	23	M
82	AP	26	F
83	MR	49	M
84	LF	52	F
85	CK	49	F

Subject Number	Subject Initials	Age	Sex
86	LH	27	F
87	AS	19	M
88	MU	48	F
89	MM	55	F
90	CM	39	M
91	DR	58	F
92	SM	45	F
93	AG	56	M
94	JI	46	M
95	RJ	55	F
96	MP	59	F
97	NA	55	M
98	CT	29	M
99	DH	25	M
100	TL	34	F
101	GL	29	M
102	KT	38	F
103	JO	45	M
104	WH	58	F
105	PP	67	F
106	WB	55	M
107	DP	40	F
108	JK	32	F
109	MV	50	F
110	DP	53	M
111	ZH	59	F
112	BG	66	F
113	HS	61	F

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Appendix II - Study JA900-DAA-5

STUDY JA900-DAA-5

TEST SAMPLE

Sample preparation: R&D
Request date: Jun 27, 2016
Test Chemical: JA900-DAA (51% in ethanol) 1st test

Test Article JA900-DAA-5-01

30	g	JA900-DAA lot# PT-917-59
67.5	g	Alcohol SD40B
202.5	g	Diethyl Phthalate (IPC 043615)
300	*g*	*Total*

Final **JA900-DAA** Concentration =30/300 x 51% = 5.1% w/w

Test Article JA900-DAA-5-02

18	g	**Distilled water**
70.5	g	Alcohol SD40B
211.5	g	Diethyl Phthalate (IPC 043615)
300	*g*	*Total*

Final **Distilled Water** Concentration= 18/300 = 6% w/w